DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

[Docket No. 01D–0025]

Guidance for Industry on FDA Recommendations for Sampling and Testing Yellow Corn and Dry-Milled Yellow Corn Shipments Intended for Human Food Use for Cry9C Protein Residues; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled "FDA Recommendations for Sampling and Testing Yellow Corn and Dry-Milled Yellow Corn Shipments Intended for Human Food Use for Cry9C Protein Residues." Cry9C is a pesticidal protein that was introduced into the StarLink™ variety of yellow corn using recombinant deoxyribonucleic acid (DNA) techniques to make the corn more resistant to certain types of insects. StarLink™ corn is lawful only for use in animal feed, not human food. However, some Cry9C-containing corn was commingled with yellow corn intended for human use. This document outlines the approach that FDA recommends to manufacturers of corn products for human food use for sampling and testing yellow corn (and milled yellow corn in certain situations) in order to minimize the production of human food products with corn containing the Cry9C protein.

DATES: Submit written comments concerning this guidance to the Dockets Management Branch (address below) by [*insert date 60 days after date of publication in the* **Federal Register**]. After [*insert date 60 days after date of publication in the* **Federal Register**], submit written comments to the contact person (address below).

ADDRESSES: Submit written comments concerning this guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD

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20852. Submit written requests for single copies of the guidance to Lauren M. Posnick, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5321. Send one self-adhesive address label to assist that office in processing your request. Comments and requests for copies should be identified with the docket number found in brackets in the heading of this document. A copy of the guidance and comments received by [*insert date 60 days after date of publication in the* **Federal Register**], are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Lauren M. Posnick, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5321, FAX 202–205–4422, e–mail: lposnick@cfsan.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is issuing guidance for industry on sampling and testing for the presence of Cry9C protein residues in yellow corn (and milled yellow corn in certain situations) intended for human food use. Cry9C is a pesticidal protein that was introduced into the StarLink™ variety of yellow corn to make the corn more resistant to certain types of insects. The Environmental Protection Agency (EPA) authorized StarLink™ corn only for use in animal feed, not human food. EPA has not authorized the use of StarLink™ corn in human food because there is an unresolved question about the allergenic potential of the Cry9C protein.

Although restricted to animal food use, some StarLink™ corn was commingled with yellow corn intended for human use. In addition, in certain limited cases, the Cry9C protein has also been detected in corn seeds of a non-StarLink™ variety of corn or in corn from such seeds. Aventis S.A., the developer of StarLink™, in cooperation with the U.S. Department of Agriculture, has been buying back harvested StarLink™ corn from the year 2000 crop to prevent its introduction into the human food supply. Because some Cry9C-containing corn may have been missed in the

buy-back program and because some StarLink™ corn from the 1999 crop may still be in some grain elevators, FDA is urging corn dry-milling and masa operations to screen yellow corn (and milled yellow corn in certain situations) to minimize the production of human food products with corn containing the Cry9C protein. Because corn containing the Cry9C pesticide is adulterated if intended for human food use (21 U.S.C. 342(a)(2)(B)), manufacturers who detect Cry9C-containing corn in any lot should divert the lot to animal feed or industrial use.

The guidance document contains FDA's recommendations to dry milling and masa operations for sampling and testing yellow corn shipments; the guidance recommends appropriate tests, representative sampling procedures, appropriate analytical procedures, and appropriate personnel training. FDA believes these recommendations will help manufacturers to identify those lots of corn that contain the StarLink™ variety commingled with other yellow corn and avoid the use of such corn in human food products.

This Level 1 guidance is being issued consistent with FDA's good guidance practices regulation (65 FR 56468, September 19, 2000). The guidance represents the agency's current thinking on sampling and testing yellow corn for residues of the Cry9C protein. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations. To the extent that use of this guidance helps millers and food manufacturers avoid the production of human food containing Cry9C residues, the guidance will help prevent human exposure to a potential food allergen and will otherwise help prevent adulteration of the food supply. Due to the urgent need to convey the sampling and testing recommendations to members of the food industry to help prevent the further introduction of Cry9C-containing corn into the human food supply, FDA conveyed the substance of this guidance to affected millers and food manufacturers in a letter dated December 27, 2000 (Ref. 1). Similarly, FDA is making this guidance document effective immediately because public participation prior to its implementation is not appropriate in these circumstances (21 CFR 10.115(g)(2); 65 FR

56478). However, in its letter of December 27, 2000, FDA recognized that some dry milling and masa operations may have inventories of stored grain or meal that have not been tested or have not been tested as described in the guidance document. Consistent with that advice, the agency is recommending that manufacturers that choose to follow this sampling guidance phase it in over a period of no more than 30 days dating from December 27, 2000.

Although the guidance document announced in this notice is being implemented immediately, FDA is requesting comments on the guidance. FDA will review all comments received, revise the guidance in response to the comments as appropriate, and publish a notice of availability of the revised guidance, if it is revised.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this immediately-in-effect guidance by [*insert date 60 days after date of publication in the* **Federal Register**]. After [*insert date 60 days after date of publication in the* **Federal Register**], submit written comments regarding this guidance to the contact person (address above). FDA will consider such comments when determining whether to revise the current guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the guidance document and comments received by [*insert date 60 days after date of publication in the* **Federal Register**], may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. An electronic version of this guidance is available on the Internet at www.cfsan.fda.gov.

III. References

The following references have been placed on display at the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday

1. Letter and recommendations, dated December 27, 2000.

2. "Sampling and testing plan, scientific basis," January, 2000.

Dated: January 12, 2001

January 12, 2001

Ann M. Witt
Acting Associate Commissioner for Policy

[FR Doc. 01–????? Filed ??–??–01; 8:45 am]

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